CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 21-135

MICROBIOLOGY REVIEW(S)

FEB 2 4 2000

REVIEW FOR HFD-180
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST'S REVIEW OF SUPPLEMENT
3 February 2000

A. 1. NDA 21-135
APPLICANT: Luitpold Pharmaceuticals, Inc.
One Luitpold Drive
Shirley, New York 11967

2. PRODUCT NAME: Venofer® (iron sucrose) Injection

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:
The product is a solution for intravenous injection. The product is supplied in 5 mL single dose vials (5 mL fill) containing 20 mg elemental iron per mL.

4. METHODS OF STERILIZATION:
The product is

5. PHARMACOLOGICAL CATEGORY and/or PRINCIPLE INDICATION:
The product is indicated in the treatment of dialysis-associated anemia.

B. 1. DATE OF INITIAL SUBMISSION: 6 August 1999

2. DATE OF AMENDMENT: (none)

3. RELATED DOCUMENTS: (none)

4. ASSIGNED FOR REVIEW: 20 September 1999

C. REMARKS: The submission provides for manufacture of the drug product at the applicant's Shirley, New York facility. Following filling the drug product vials

D. CONCLUSIONS: The application is approvable upon resolution of microbiology concerns.

/S/ 3 February 2000
Paul Stinavage, Ph.D.

cc: Original NDA 21-135
HFD-180/B. Strongin/Division File
HFD-805/Consult File/Stinavage

Drafted by: P. Stinavage, 3 February 2000
R/D initialed by P. Cooney

/S/ for PHC 2/24/2000

APPEARS THIS WAY
ON ORIGINAL

Strongin

REVIEW FOR HFD-180
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST'S REVIEW #2 OF NDA 21-135
29 August 2000

AUG 29 1999

A. 1. NDA 21-135 BC
APPLICANT: Luitpold Pharmaceuticals, Inc.
One Luitpold Drive
Shirley, New York 11967

2. PRODUCT NAME: Venofer® (iron sucrose) Injection

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:
The product is a solution for intravenous injection. The product is supplied in 5 mL single dose vials (5 mL fill) containing 20 mg elemental iron per mL.

4. METHODS OF STERILIZATION:
The product is [redacted]

5. PHARMACOLOGICAL CATEGORY and/or PRINCIPLE INDICATION:
The product is indicated in the treatment of dialysis-associated anemia.

B. 1. DATE OF INITIAL SUBMISSION: 6 August 1999

2. DATE OF AMENDMENT: 20 June 2000 (Subject of this Review)

3. RELATED DOCUMENTS: (none)

4. ASSIGNED FOR REVIEW: 20 July 2000

C. REMARKS: The submission provides for manufacture of the drug product at the applicant's Shirley, New York facility. Following filling the drug product vials [redacted]

D. CONCLUSIONS: The application is recommended for approval on the basis of sterility assurance.

/S/ 29 August 2000
Paul Stinavage, Ph.D.
/S/ 8/29/00

cc: Original NDA 21-135
HFD-180/B. Strongin/Division File
HFD-805/Consult File/Stinavage

Drafted by: P. Stinavage, 29 August 2000
R/D initialed by P. Cooney

APPEARS THIS WAY
ON ORIGINAL